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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,264	10/27/2003	Geoffrey A. Russell	NA1.031	2808
23893	7590	05/26/2005	EXAMINER	
TIMOTHY E SIEGEL 1868 KNAPPS ALLEY SUITE 206 WEST LINN, OR 97068			MALLARI, PATRICIA C	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/694,264	Applicant(s) RUSSELL ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/11/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 2-25 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected election, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/2/05.

Claim Objections

Claims 1 and 27-29 objected to because of the following informalities:

In claim 1, items b and c appear to be parts of the measuring device rather than steps of the method. Therefore, "(b)" and "(c)" should be replaced with "(i)" and "(ii)". Additionally, "(d)", "(e)", "(f)", "(g)", and "(h)" should be replaced with "(b)", "(c)", "(d)", "(e)", and "(f)", respectively.

On line 3 of claim 27, "said enzyme" should be replaced with "an enzyme";

On line 3 of claim 28, "said enzyme" should be replaced with "an enzyme";

On line 3 of claim 29, "said enzyme" should be replaced with "an enzyme".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,793,632 to Sohrab. Sohrab incorporates US Patent No. 6,193,873 to Ohara et al. by reference (col. 13, lines 46-49 of Sohrab). Sohrab discloses a method of measuring an analyte concentration in a body fluid of an animal body having skin and subcutaneous soft tissue that includes body fluid. The method comprises providing an analyte measuring device (col. 13, lines 5-10 of Sohrab). The device includes an analyte sensing element 100, 200 having a sharpened distal end 102, 202 to facilitate introduction into the body (figs. 1A & 2A; col. 7, lines 39-42 of Sohrab) and further having an indicating electrode 108, 112, 208, 212 (col. 8, lines 32-37; col. 9, lines 37-49 of Sohrab) covered by an absorbent layer (col. 8, lines 48-53; col. 10, lines 6-17 of Sohrab). The device also includes an electric power, data processing and display device 52 adapted to mate to the analyte sensing element 100, 200 (fig. 4; col. 12, lines 30-51 of Sohrab) and activate the sensing element by applying electric power to it (col. 13, lines 46-49 of Sohrab; col. 2, lines 41-54 of Ohara; col. 4, lines 49-56 of Ohara). The power, data processing and display device 52 also is adapted to receive the raw analyte measurement (the output signal level) and to compute and display a refined analyte measurement (analyte concentration) related to the raw measurement (col. 13, lines 30-37 of Sohrab). The analyte sensing element 100, 200 is introduced into the body tissue, thereby placing the absorbent layer into contact with the soft tissue and body fluid (col. 13, lines 13-20 of Sohrab). The absorbent layer saturates with body fluids (col. 13, lines 21-25 of Sohrab). While a step of removing the electrode 108, 112, 208, 212 is not explicitly stated, such removal is inherent, as the device of Sohrab is

clearly not a permanently implanted device. The analyte sensing element 100, 200 is activated by applying electric power, thereby causing the element to form a raw analyte measurement (col. 13, lines 25-30 and lines 46-49 of Sohrab; col. 2, lines 41-54 of Ohara; col. 4, lines 49-56 of Ohara). The electric power, data processing and display device 52 receives the raw measurement and computes and display a refined analyte measurement related to the raw measurement (col. 13, lines 31-37 of Sohrab).

Regarding claim 26, an enzyme layer is interposed between the indicating electrode 108, 112, 208, 212 and the absorbent layer (col. 11, lines 22-29 and lines 35-36 of Sohrab).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sohrab, as applied to claims 1 and 26 above, and further in view of US Patent No. 4,953,552 to DeMarzo. Sohrab discloses a reagent system including an enzyme and a mediator, the reagent system being located between the electrode and the absorbent layer (col. 11, lines 21-36 of Sohrab). Sohrab is silent as to an order of the enzyme layer and the mediator layer with respect to the electrode. However, DeMarzo discloses an analyte sensing element configured to be inserted into the skin and soft tissue of a user. The sensing element comprises a redox mediator layer 68 interposed between the enzyme

layer 70 and the electrode 54 (fig. 5; col. 4, lines 4-10 of DeMarzo). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to dispose the enzyme and redox layers of Sohrab in the order shown by DeMarzo in order to immobilize the enzyme on the electrode (col. 4, lines 9-10 of DeMarzo).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sohrab, as applied to claims 1 and 26 above, and further in view of US Patent No. 6,083,710 to Heller. Sohrab lacks a permselective layer between the enzyme and the absorbent layers. However, Heller discloses an analyte sensing element comprising a permselective layer 10 interposed between the enzyme layer 8 and the absorbent layer 14 (fig. 1; col. 4, lines 16-23; col. 5, lines 47-55; col. 6, lines 16-24 of Heller). Therefore, it would have been obvious to one of ordinary skill in the art to combine the element of Heller with the method of Sohrab in order to provide more accurate analyte measurements (col. 3, lines 7-16; col. 5, lines 48-50 of Heller).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sohrab, as applied to claims 1 and 26 above, and further in view of Heller. Sohrab lacks an interferent excluding layer between the enzyme and absorbent layers. However, Heller discloses an analyte sensing element comprising an interferent excluding layer 12 interposed between an enzyme layer 8 and an absorbent layer 14 (fig. 1; col. 4, lines 15-23; col. 5, line 62-col. 6, line 24 of Heller). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the element of Heller with the method of Sohrab in order to make one-point in vivo calibration of the sensor possible (col. 3, lines 16-18 of Heller).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 4,711,245 to Higgins et al.


US Patent No. 4,671,288 to Gough.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
Patent Examiner
Art Unit 3736


ROBERT L. NASSER
PRIMARY EXAMINER